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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,428	10/15/2001	Peter Unger	B0048-US02	5257

24994 7590 05/06/2003

GAMBRO, INC
PATENT DEPARTMENT
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LAKEWOOD, CO 80215

EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,428

Applicant(s)

Unger et al.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 24, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-11 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Oct 15, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____ 6) ☐ Other:

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1. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842. WO95/01842 teaches a method of separating cells in a centrifuge comprising providing buffy coat in a processing bag (1) in a centrifuge, separating buffy coat into thrombocyte-rich plasma (i.e. light-weight fraction enriched with platelets), transferring thrombocyte-rich plasma to a storage bag (2) via an outlet tube (3) in a position having a radially inwardly and outwardly directed flow and having an opened clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary surface of the phase in the outlet tube (3) wherein buffy coat inherently includes platelets and red blood cells (see page 8, line 29 - page 10, line 31). Claims 1-3 and 6-8 essentially differ from the method of WO95/01842 in reciting that activation of valve into open position during centrifugation. WO95/01842 teaches that thrombocyte-rich plasma is transferred to a storage bag (2) via an outlet tube (3) having a clamp valve (38) during on-going centrifugation (see page 10, lines 1-31). Activating clamp valve into an open position during on-going centrifugation is a necessary step to successfully transfer thrombocyte-rich plasma from a processing bag (1) to a storage bag (2) during centrifugation would have been obvious to a person of ordinary skill in the art.

2. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO95/01842 as applied to claim 1 above, and further in view of U.S. Patent No. 5,116,308 (hereinafter referred to as Hagiwara et al). WO95/01842 teaches clamp valve (38) responding to the programmed operation of the centrifuge and/or photocells which detect the displacement of the boundary

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surface of the phase in the outlet tube (see page 9, lines 4-11). Hagiwara et al teach the use of manually clamp (41) or electromagnetic valve (41) which are well-known in the art to control the flow of the fluid in an outlet tube from a blood treatment apparatus (see 41 in Figure 2; col. 10, lines 11-25). It would have been obvious to a person of ordinary skill in the art to substitute well-known manually activatable clamp or magnetically activatable valve or electromagnetically activatable valve for a valve in the outlet tube in the method of WO95/01842 to control the flow of enriched fraction to a storage bag.

3. Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Applicant's arguments with respect to claims 1 and 3-11 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
May 1, 2003